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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,053	12/21/2001	James A. Brady	9386.17711-F	5771

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EXAMINER

BIANCO, PATRICIA

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 06/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/038,053

Applicant(s)

BRADY ET AL.

Examiner

Patricia M. Bianco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-45 is/are pending in the application.
- 4a) Of the above claim(s) 33-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5/04; 9/03; 7/03; 4/03; 4/03
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Species G, figures 10A-10B, claims 17-45, in the amendment filed 3/01/06 acknowledged.

Claims 33-45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species (i.e. figure 13), there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 3/01/06.

The examiner has withdrawn claims 33-45 since the elected embodiment, figures 10A/10B, do not disclose the first unit comprising a first material for removing a target compound, but rather only discloses that the first unit is a blood processing element.

Applicant cancelled claims 1-16 in the response filed 3/01/06; as a result, claims 17-45 remain pending, claims 33-45 are withdrawn, and claims 17-32 have been examined on the merits.

Specification

Applicant has indicated co-pending applications in the first paragraph of the specification. The first page of the specification should be updated to clarify the **status** of all related applications noted in the first paragraph of the specification. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent

No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

The disclosure is objected to because of the following informalities: It is the Examiner's position that Applicant has evoked sixth paragraph, means-plus-function language to define Applicant's invention. Therefore the Examiner requires the Applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o) to explicitly state, with reference to the terms and phrases of the claim element, what structure, materials, and acts perform the function recited in the claim element. Please note that the MPEP clearly states, "Even if the disclosure implicitly sets forth the structure, materials, or acts corresponding to the means-(or step-) plus-function claim element in compliance with 35 U.S.C. 112, first and second paragraphs, the PTO may still require the applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o)...". (Also see **MPEP 2181** (Rev. 1, Feb.2000)) *Wolfensperger*, 302 F.2d at 955, 133 USPQ at 542. For example, applicant recites "coupling means" in the claims.

Appropriate correction is required.

Claim Objections

Claims **17-19 and 33-38 are objected** to because of the following informalities:
It is the Examiner's position that Applicant has evoked sixth paragraph, means-plus-

function language to define Applicant's invention. Therefore the Examiner has objected to the claims for the reasons set forth above in the objection to the specification.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 17-19, 22-28, 31, and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Matson et al. (6,287,516). Matson et al. (hereafter Matson) discloses a blood treatment system that includes a hemofiltration system (i.e. first unit for processing the blood) and an adsorbant system (i.e. second unit) including an adsorbant material and tubing connecting (i.e. a coupling means) the first and second units to make a single, integrated unit. The first unit, a hemofilter, separates the blood into components. With respect to claims 18 and 19, Matson shows in the figures that the first unit is upstream of the second unit, however, Matson also teaches that the arrangement may be rearranged (col. 17). The adsorbant material comprises many different copolymer materials, such as a copolymer including alkyl methacrylate as a monomer (see col. 12) and the adsorbant material may have a coating (col. 13) or be a

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matrix (col. 6). The system is used for removing inflammatory mediators (i.e. cytokines) or mid weight MW proteins from a body fluid.. With respect to the claimed limitations of claims 25-28, the recitation that the polymeric material is "prepared by" or "formed from" a process has not been given patentable weight since it is a product-by-process limitation. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matson et al. ('516). Matson discloses the invention substantially as claimed, see rejection supra, however, fails to disclose specifically that the adsorption medium is characterized by a Biocompatibility Index of not greater than 14, or not greater than 7. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the polymeric material of the adsorbant in Matson's device to be characterized by a Biocompatibility Index of not greater than 14, or not greater than 7, since it has been held in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Matson et al. ('516). Matson discloses the invention as claimed, see rejection supra, however, fails to disclose specifically that the first unit is configured to separate the blood removed into components.

Davankov et al. (5,773,384) discloses a system for extracorporeally removing toxins, such as cytokines, from blood using an adsorbent material held in a housing. Davankov teaches that blood is withdrawn from a blood vessel and first separated by a separation membrane, such as a centrifuge, and passed through a column holding the

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adsorbent material within a housing or cartridge. The adsorbent is a biocompatible, polymeric material such as polystyrene resin, copolymers of methacryloyloxethyle or styrene-divinylbenzene copolymers.

At the time of the invention, it would have been obvious to one having ordinary skill in the art to have substituted a centrifuge for the hemofilter in Matson prior to separation though the adsorbant material as a substitution of parts, since applicant has set forth no criticality as to the structure and function of the first unit and both a hemofilter and a centrifuge separate whole blood.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Matson et al. ('516). Matson discloses the invention as claimed, see rejection supra, however, fails to disclose specifically that the first unit is configured to oxygenate the blood.

Okarma et al. (5,730,713) discloses a system for extracorporeally removing toxins, such as cytokines, from blood using an adsorbent material held in a housing. Okarma also teaches that it is typical that this therapy also involves oxygenation of the blood is withdrawn. At the time of the invention, it would have been obvious to one having ordinary skill in the art to have substituted an oxygenator for the hemofilter in Matson prior to separation though the adsorbant material as a substitution of parts, since applicant has set forth no criticality as to the structure and function of the first unit to be an oxygenator.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia M. Bianco whose telephone number is (571) 272-4940. The examiner can normally be reached on Monday to Friday 9:00-6:30, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

May 30th, 2006

Patricia M Bianco
Primary Examiner
Art Unit 3761

